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As Cooperative Groups Pursue Contracts With Insurers, NCI Warns Of Competition

NCI is not alone in negotiating deals with third party payers over coverage of patient care costs of clinical trials.

While the Institute is working on agreements similar to the "demonstration project" with the Department of Defense health system (**The Cancer Letter**, Feb. 9), the clinical trials cooperative groups are not standing still.

In fact, several groups are doing some aggressive deal-making of their own.

Would these concurrent negotiations produce a maze of agreements

(Continued to page 2)

In Brief

Allegheny Wins NSABP Recompetition; Lurie Cancer Center Hosts Princess Diana

NATIONAL SURGICAL ADJUVANT BREAST & BOWEL PROJECT has successfully recompeted for NCI grants for the cooperative group's chemoprevention and therapy trials, sources said. The group's chemoprevention grant was renewed for five years and the therapy grant was renewed for four years. The chairman and operations offices will be based at **Allegheny General Hospital**; the grantee is the Allegheny-Singer Research Institute. **Norman Wolmark**, director of the Allegheny Cancer Center, is the principal investigator. The group's biostatistics office will remain at the University of Pittsburgh, with **Sam Wieand** as the principal investigator. . . . **PRINCESS DIANA** made opening remarks at a breast cancer symposium conducted by the **Robert H. Lurie Cancer Center** at Northwestern University on June 5. Her 48-hour visit to Chicago was expected to help raise more than $1 million for cancer research through ticket sales to a lunch and black-tie dinner. The funds are to be shared equally by the Lurie Center, the Royal Marsden Hospital of London, and Gilda's Club, a New York-based ovarian cancer support group named for the late actress Gilda Radner. . . . **ELI GLATSTEIN** has left the position of chairman of radiation oncology at University of Texas Southwestern Medical Center in Dallas to become vice-chairman and clinical director of the Department of Radiation Oncology at the University of Pennsylvania in Philadelphia. Glatstein was the former chief of the NCI Radiation Oncology Branch from 1977-1992.

Cooperative Groups Explore Agreements With Payers

(Continued from page 1)

that could be less functional than the existing system?

It could, warned Robert Wittes, director of the NCI Division of Cancer Treatment, Diagnosis and Centers.

"We see it as very deleterious if the groups start competing with each other to cut deals with individual payers," Wittes said at a meeting of cooperative group chairmen June 7. "This might result in a different outcome than you intend."

In a subsequent interview with **The Cancer Letter** Wittes said he fears that cooperative groups could become competitive with each other, following in the footsteps of the cancer centers that in some markets vie for the same patients and the same managed care contracts.

"There's nothing at all wrong with individual groups having exploratory discussions with payers about various models that might be used to ensure reimbursement," Wittes said in an interview. "But the groups really must act together, they mustn't act competitively."

Unlike the cancer centers, the cooperative groups must retain their national scope, Wittes said.

"A certain amount of jockeying for position is inevitable," he said. "There is going to be competition between individual institutions. We don't want the cooperative groups to [compete with each other], because the program of multicenter clinical trials is a national program," Wittes said.

"The problem is a national problem, so the solution should be a national solution," he said.

ECOG Goal To Move Pediatric Model to Adults

At the meeting last week, group chairmen discussed their efforts to forge agreements with insurers, and NCI officials provided an update on the demonstration project with DOD and talks with other payers.

The Eastern Cooperative Oncology Group has recruited an official from the Blue Cross/Blue Shield Association to help the group forge agreements with insurers for coverage of patient care costs in clinical trials, said Robert Comis, chairman of the group.

Andrew Kelahan, the former BCBS official who was instrumental in the formation of the Pediatric Cancer Network, is now working with ECOG to expand the pediatric model to adult cancer patients.

The Pediatric Cancer Network offers cancer care and clinical trials to children in the Blues plans around the country (**The Cancer Letter**, April 19). The network includes member institutions of the Pediatric Oncology Group and the Children's Cancer Group.

Kelahan said he became interested in cancer clinical trials as a result of frequent discussions with POG chairman Sharon Murphy, whose office is located across the street from the BCBS offices in Chicago.

"It's easiest to start with kids because everyone wants to do right by kids," Kelahan said to the group chairmen. "The hard part is to take it to adults."

ECOG is starting to talk with BCBS and other insurers, Kelahan said. In these discussions, semantics are important. "Part of the process is to help the [insurers] re-define what is research, to change the language of the contract," Kelahan said.

"We don't say 'trials' anymore," he said. "We talk more in terms of a network of quality institutions providing quality cancer care."

The Pediatric Network will certify institutions using POG and CCG standards, he said. Kelahan said his current goal is to strike a series of deals for support of patient care costs for all ECOG trials.

Specter of Fragmentation?

Reacting to the ECOG plan, several cooperative

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group chairmen said such deals have the potential to backfire.

Charles Coltman, chairman of the Southwest Oncology Group, said he feared the groups would become fragmented over such agreements. "If we start doing multiple deals, things are going to get very confusing," Coltman said. "I worry about payers getting a mixed message, one from [ECOG] and one from NCI."

James Cox, chairman of the Radiation Therapy Oncology Group, questioned whether the agreements should be structured to approve care at specific institutions.

"I'm concerned that by credentialing institutions rather than trials, you open the floodgate to all sorts of treatment that could be sanctioned just because it happens at the right institution," Cox said.

"We don't want every institution's study to be covered," Comis replied.

"This is a first cut at things," Kelahan said. "Major insurers are interested, and they want to get something done."

Wittes said Kelahan was invited to speak precisely because his presentation was certain to provoke discussion.

"The risk of an unintended outcome is minimized if you keep the other chairmen informed and keep things out in the open and make sure everyone can benefit," Wittes said to the group chairmen.

In a subsequent interview Wittes said the Pediatric Network model may be difficult to implement for adults with cancer.

"Pediatric cancer is rare, pediatric oncology expertise is concentrated in relatively few places, and is heavily based in academic centers," Wittes said to **The Cancer Letter**. "A high proportion of children with cancer are placed on clinical trials, so it is easy to envision a network of excellence for pediatric cancer that is based on concepts of clinical excellence, but also heavily emphasizes clinical trials.

"By contrast, adult cancer is common, there is a very large number of oncologists dealing with adult cancer, and they are heavily represented throughout the community as well as academic health centers. And only a very small percentage of adults with cancer enter clinical trials," Wittes said.

CHAMPUS Patients Enter Trials

Over the past four months NCI officials have been working with the DOD health system, called the Civilian Health and Medical Program of the Uniformed Services (CHAMPUS) to begin placing military personnel and dependents on NCI-sponsored phase II and III studies.

Since the NCI-DOD project was announced, 31 CHAMPUS patients have been reviewed for potential eligibility, Mary McCabe, special assistant to Wittes, said to the cooperative group chairmen.

Of those patients, 26 have been approved for entry onto trials, she said.

Eleven patients were entered onto cooperative group studies, 11 on cancer center studies, and four on NCI-funded grant studies, McCabe said. Looking at accrual by study phase, 16 patients are in phase II studies and 10 are entered onto phase III studies.

NCI staff have acted as case managers with CHAMPUS patients to facilitate their entry onto trials and to promote the availability of trials, McCabe said. "This also helps to build goodwill with CHAMPUS physicians," McCabe said.

The Institute and DOD have yet to begin full-scale promotion of the availability of trials to CHAMPUS physicians and beneficiaries, McCabe said.

However, NCI has improved the search function in its Physician's Data Query database to enable computer users to search for clinical trials by sponsorship category. If a CHAMPUS physician or patient calls the Cancer Information Service, or logs on to the PDQ database, they will be able to search for NCI-sponsored studies and obtain a complete listing.

In addition, NCI officials met with military physicians during the annual meeting of the American Society of Clinical Oncology last month. Some military physicians are concerned that the CHAMPUS agreement will divert their patients to civilian hospitals, McCabe said.

About eight to 10 military hospitals work with the NCI cooperative groups. The military hospitals can join cooperative groups or can take part in the NCI Community Clinical Oncology Program.

"We would like to see the military hospitals have a more extensive involvement in clinical trials," McCabe said. "We want this program to be additive." The CHAMPUS agreement specifies that if an NCI-sponsored trial is available at a military facility and the patient has access to that facility, then the military

facility will have the first option of enrolling the patient on the trial, McCabe said.

NCI is working to update the PDQ listing of military hospitals that have active cooperative group protocols. This would enhance accrual of patients to protocols at military hospitals and provide recognition for their cooperative group participation, McCabe said.

NCI Discussions With VA, HCFA

McCabe said NCI's discussions with various private insurers are continuing.

"We are discussing those areas where we have common ground," she said.

NCI is in discussions with the Veterans Administration to forge an agreement on coverage of clinical trials. "The meetings have been very productive," McCabe said. "We expect something successful will come of it."

The deal with VA may be different from the CHAMPUS agreement because the VA is a health care provider as well as a payer, McCabe said. VA hospitals have affiliations with the cooperative groups and cancer centers.

"We want to talk to the Veterans Administration about strengthening those affiliations, and think of ways to offer trials in addition to those efforts," McCabe said.

NCI's discussions with the Health Care Financing Administration have gone more slowly, McCabe said. "They are a difficult agency to have discussions with, because there is a sense that we are asking them to expand coverage at a time when the projections indicate the Medicare trust fund will be out of money sometime early in the next century."

HCFA has agreed to cover Medicare patients entered onto a study sponsored by the National Heart, Lung and Blood Institute. However, NCI's goal continues to be reimbursement for patient care costs for all clinical trials, McCabe said.

"We certainly want more [coverage] than just a trial here and there," she said.

Create Demand; Speed Trial Reviews

Approaching the insurance coverage problem from another perspective, NCI officials have begun working with patient advocacy groups to "create demand" for clinical trials, McCabe said.

McCabe and Wittes met last month with representatives from 24 cancer patient advocacy groups as well as ASCO and the Oncology Nursing Society to develop strategies for public education about the importance of clinical trials.

NCI will involve patient advocates in clinical trials promotion and education activities, including the DOD project, McCabe said.

The Institute also plans to post a clinical trials page on the World Wide Web.

"We need to continue to sell this notion that access to clinical trials is access to quality care," Wittes said to the group chairmen. "Clinical trials should be seen as access to dynamic practice guidelines."

However, the clinical trials system needs to complete trials faster and get answers sooner, Wittes said.

The Cancer Therapy Evaluation Program, which oversees NCI-sponsored clinical trials, will examine all aspects of its policies and procedures to determine how to speed protocol reviews, Wittes said.

The division also plans to create an outcomes branch to improve the body of knowledge on outcomes of cancer patients who enter clinical trials. This data is lacking, thus hampering NCI's ability to sell insurers on the benefits of supporting patients on trials, Wittes said.

Caterpillar Inc. To Cover BMT Trials For Breast Cancer

Caterpillar Inc., the mining and construction equipment manufacturer, based in Peoria, IL, has agreed to cover the patient care costs of placing employees or dependents with breast cancer on three NCI-sponsored trials of bone marrow transplantation.

The company made the decision following a discussion between Rick Luetkemeyer, the Caterpillar corporate medical director and NCI officials, said Mary McCabe, special assistant to Robert Wittes, director of the NCI Division of Cancer Treatment, Diagnosis and Centers.

Luetkemeyer had called NCI last March for information about cancer clinical trials, McCabe said at a meeting of chairmen of NCI cooperative groups June 7.

Officials at Caterpillar, a company that insures 150,000 individuals, estimate that each year, an

average of 130 employees or dependents are diagnosed with breast cancer. The company's benefits plan did not cover bone marrow transplantation.

McCabe said the company will provide coverage for the two intergroup studies for women with high-risk disease (INT-0121 and INT-0163), as well as for the new study scheduled to begin next month for breast cancer patients with four to nine involved nodes (S9623) (descriptions of the studies were published in **The Cancer Letter**, June 7).

The company will not cover entry onto BPT01, also known as the Philadelphia study, for metastatic disease.

"Another Option In Fight Against Disease"

In a letter to employees, the company did not list the three trials specifically, but referred to "select" NCI-sponsored studies of new treatments for breast cancer.

"The decision whether or not to pursue this option will be made by the patient in consultation with the patient's doctor and the NCI," Wayne Zimmerman, Caterpillar's vice president, human services, said in a letter dated May 20. "And all who participate in one of these clinical studies will have the benefit of dealing with specialists who are at the very forefront of breast cancer research.

"Our decision to help fund these experimental treatments will give at least some Caterpillar employees and their families another option in their fight against this disease," Zimmerman wrote. "We also hope it will help the medical community make significant advances in breast cancer treatment."

McCabe said the company's benefit plan will send a letter to each breast cancer patient's physician informing them of the coverage for BMT trials. The letter will include information prepared by the NCI Office of Cancer Communications.

NCI Bypass Budget Published, Seeks $2.7 Billion In FY98

Traditionally, the release of the NCI Bypass Budget, a document that routinely broke the 500-page barrier, has been the non-event of the year.

Not so with the slim, 80-page version of the budget that outlines the opportunities in cancer research.

"The document speaks to the entire country," HHS Secretary Donna Shalala said of the 1997-1998 bypass budget that was officially released last week. "It gives us all a grounding in the astonishing new knowledge of how cancer cells work and how that knowledge translates into solid hope that we can reduce the awful burden of cancer."

In the budget, NCI sets forth the funds needed for the next two fiscal years. Unlike previous Bypass Budgets, the new document outlines two levels of investment in cancer research.

Level 1, $2.28 billion in fiscal year 1997 and $2.43 billion for FY98, is adequate for current research to advance.

Level 2, $2.7 billion in FY98 would enable NCI to expand five crucial new areas of research (**The Cancer Letter**, March 29).

Five Crucial Areas Listed

NCI Director Richard Klausner said four of the five new research opportunities spring from recent discoveries aobut the basic biology of cancer cells:

--Cancer genetics. Goals in this area are to identify every major human gene that predisposes people to cancer; to use this information to transform medical practice; and to identify and solve psychosocial, ethical, and legal issues associated with cancer genetics.

--Preclinical models of cancer. Technical advances in animal genetics enable the study of cancer in ways that were not possible a few years ago, the budget document said. The goal is to breed genetically modified animals that will aid in research on human cancer based on emerging knowledge of human cancer genes.

--Detection technologies. Goals are to use the new understanding of cancer cells and molecules to detect tumors at the earliest possible stage, and to discover and develop new diagnostic imaging techniques and integrate imaging furhter into clinical practice.

--Developmental diagnostics. The goals is to develop diagnostic tests based on a tumor's cells, molecules, and genes, allowing physicians to tailor therapy to that tumor and to predict how it will react to therapy.

The fifth area reflects NCI's belief that progress in cancer research is tied to the work of individual scientists in laboratories around the country, NCI said in a statement. This "engine of discovery" must be

fueled and maintained.

--Investigator-initiated research. The goals here are to accelerate the pace of discovery and to increase opportunities for individuals to conduct cancer research.

"These are milestones we can achieve, not promises we cannot keep," Klausner said.

The new Bypass Budget is designed for readers outside the Institute, but also reflects NCI's drive to bring people into the Institute's planning process, NCI said.

The document is available through the NCI Cancer Information Service: 800/4-CANCER (800/422-6237).

NIH Advisors Recommend Revamping Peer Review

An advisory group formed to review the NIH procedures for rating grant applications has recommended a 10-step plan for revamping peer review.

The recommendations of the Subcommittee on Rating of Grant Applications were contained in a report that was released by NIH officials, who said they are inviting comments from extramural researchers.

The subcommittee is part of the NIH Committee on Improving Peer Review.

NIH plans to revamp the grant review system by January 1997 and have it in place for the review of grant applications to be funded in fiscal year 1998.

Three New Criteria Proposed

The group's recommendations are:

1. Unsolicited research project grant applications should be reviewed in accordance with the following criteria:

Significance. The extent to which the project, if successfully carried out, will make an original and important contribution to biomedical or behavioral science.

Approach. The extent to which the conceptual framework design (including the selection of appropriate subject populations or animal models), methods, and analyses are properly developed, well-integrated, and appropriate to the aims of the project.

Feasibility. The likelihood that the proposed work can be accomplished by the investigators, given their documented experience and expertise, past progress, preliminary data, requested and available resources, institutional commitment, and documented access to special reagents or technologies and adequacy of plans for the recruitment and retention of subjects.

2. Reviews should be conducted criterion by criterion, and the reviewers' written critiques should address each criterion separately.

3. Applications should receive a separate numerical rating on each criterion.

4. Reviewers should not make global ratings of scientific merit.

5. The rating scale should be defined so that larger numerical values represent greater degrees of the characteristic being rated and the smaller values represent smaller degrees.

6. The number of scale positions should be commensurate with the number of discriminations that reviewers can reliably make in the characteristic being rated. An eight-step scale (0-7) is recommended on the basis of the psychometric literature; however, a maximum of 11 steps (O-10) are acceptable.

7. The rating scale should be anchored only at the ends. The performance of end-anchors should be evaluated and other approaches to anchoring should be investigated as needed.

8. Scores should be standardized on each criterion within reviewer and then averaged across reviewers. The exact parameters for this standardization should be defined by an appropriately constituted group.

9. Scores should be reported on the scale used by reviewers in making the original ratings. Scores should be reported with an implied precision commensurate with the information contained in the scores. Two significant digits are recommended.

10. If a single score is required that represents overall merit, it should be computed from the three criterion scores using an algorithm that is common to all applications. The committee favors the arithmetic average of the three scores; however, an appropriately constituted group should test and choose the algorithm to be used.

Comments Due Oct. 1

The report is available on the NIH home page (http://www.nih.gov/grants/rga.htm), or from Diane Bronzert at the NCI Cancer Therapy Evaluation Program, tel: 301/496-8866. Comments should be sent to dder@nih.gov by Oct. 1.

American Cancer Society Clinical Fellowships Available

The American Cancer Society, California Division, announces the availability of two-year clinical postdoctoral fellowships directed to the development of clinically oriented investigators in cancer research.

The fellowships will expand the society's postdoctoral fellowship program which has been primarily oriented toward fellowships involved in basic research.

This clinical fellowship program is expected to be in place for the fiscal year 1996-97 and 1997-98. A funding set-aside of up to $300,000 will be available in fiscal 1996-97 to fund high-quality applications received in response to this request for applications.

Clinical Research Fellowship applications will be accepted in the following areas:

--Epidemiologic Research

--Preclinical Research

--Clinical Research

--Psychosocial and Behavioral Research

The maximum award in year 1 is $32,000 and in year 2, $34,000. The fellowships are not renewable. Supplementation of salary by the supporting institution is allowed for teaching and clinical activities and should be identified at the time the application is submitted for assessment during the peer review process.

Candidates need not be U.S. citizens or California residents. Information on imigration and visa status must be included with the application.

Candidates who would qualify as a principal investigator or who have an appointment equal to a faculty position are not eligible to apply.

Applicants must submit a letter of intent to the California Division Research Fellowship Program by Sept. 3. The letter should be no more than one page and should provide a brief outline of the training and research proposed. The letter must be signed by the fellow and the sponsor.

The application deadline is Nov. 1. Awards will be made in March 1997.

Inquiries: Research Fellowship Program, American Cancer Society, California Division, PO Box 2061, Oakland, CA 94604, tel: 510/893-7900.

Oncology Nursing Society Continues Fatigue Project

The Oncology Nursing Society and the Oncology Nursing Foundation have moved to phase II of its Fatigue Initiative Through Research and Education Project (FIRE).

The project, funded by Ortho Biotech, of Raritan, NJ, supports educational and research projects in cancer-related fatigue.

Three awards of $500,000 will be awarded in phase II of the project.

The society also will sponsor a conference to review cancer-related fatigue literature and make recommendations for interventions and research. A supplement to Oncology Nursing Forum will publish a fatigue professional education course held last year.

The FIRE project was begun in 1994.

For information on the project, contact ONS, tel: 412/921-7373.

Letter to the Editor:

Palestinian Authority Not Yet A "Country;" Talks Beginning

To the Editor:

In the May 24 issue of **The Cancer Letter**, a first page article on the formation of the Middle East Cancer Consortium begins as follows:

"Five Middle East countries agreed to form a consortium for cancer control activities. Ministers of health of Cyprus, Egypt, Israel, Jordan and the Palestinian Authority signed an agreement May 20 in Geneva to create the Middle East Cancer Consortium."

While I applaud the cooperation between Israel, the Palestinian Authority and their neighbors in this project, it is clearly inaccurate and premature to characterize the Palestinian Authority as a country. The final status talks that will determine whether Gaza and the autonomous regions of the West Bank become a state have only just begun.

I suspect that your article reflects editorial carelessness rather than a deliberate attempt at politicizing this issue.

Richard Baehr
Highland Park, IL

Program Announcement

PA-96-056

Title: **Postdoctoral Training In Complementary/ Alternative Medicine**

Application Receipt Dates: April 5, Aug. 5, Dec. 5

The Office of Alternative Medicine is planning to fund, through the various Institutes and Centers at NIH, National Research Service Award individual postdoctoral fellowships (F32). The purpose is to provide a cadre of investigators capable of conducting systematic studies on safety, efficacy, cost-effectiveness, or mechanisms of action of unconventional methods for treating major diseases and promoting well-being. This training is expected to attract postdoctoral candidates who are in the early stages of their careers. They will have obtained expertise in conventional research methodology and some familiarity with/or interest in alternative medical procedures. Prospective trainees will be expected to form an alliance with established researchers to provide a mutual learning experience. This PA is based on a larger, NIH-wide PA on NRSA Individual Postdoctoral Fellowships, which should be requested from the contact person listed below.

Individuals may request up to three years of aggregate NRSA support at the postdoctoral level. The stipend level for the first year of NRSA support is determined by the number of years of relevant postdoctoral experience at the time the award is issued. The range of support is from $18,600 (less than one full year of experience) to $32,300 (seven or more years of experience). Relevant experience includes research experience, teaching, internship, residency, and clinical duties. Supplementation, when provided, must not require obligation from the fellow. Under no circumstances may PHS grant funds be used for supplementation. NIH will provide an institutional allowance of $3,000 per 12-month period to non-federal non-profit sponsoring institutions to help defray such awardee expenses as tuition and fees, self-only health insurance, research supplies, equipment, travel to scientific meetings, and related items. For individuals sponsored by Federal laboratories, or for-profit institutions, the NIH will provide up to $2,000 for scientific meeting travel expenses, self-only health insurance, tuition fees, and books. Fellows in the first 12 months of postdoctoral NRSA support will incur a service obligation of one month for each month of support.

Inquiries: The PA may be obtained electronically through the NIH Grant Line (data line 301/402-2221), the NIH GOPHER (gopher.nih.gov), and the NIH Website (http://www.nih.gov), and from: Dr. Richard Nahin, Office of Alternative Medicine, NIH, Bldg 31 Rm 5B36, Bethesda, MD 20892, tel: 301/496-4792, fax: 301/402-4741, e-mail: nahinr@od31em1.od.nih.gov

RFP Available

RFP NCI-CM-77017-28

Title: **Development of dosage forms and delivery systems for anti-tumor and anti-AIDS agents**

Deadline: Approximately Aug. 26

The Pharmaceutical Resources Branch of the NCI Developmental Therapeutics Program is seeking contractors to develop acceptable dosage forms for compounds to be subsequently evaluated in cancer and HIV patients and to carry out innovative studies leading to more effective approaches for the intravenous delivery of compounds that possess limited solubility and/or stability. NCI will select and provide the compounds to be studied. The projects will require considerable analytical work, particularly the development of a stability-indicating assay to monitor the integrity of the parent compound during the formulation studies. These investigations will be directed toward a pharmaceutical dosage form that will meet certain solubility and stability targets determined by the government. The principal investigator should possess a Ph.D. in pharmaceutics or medicinal chemistry and should also have at least three years experience in the development of injectable formulations. Three cost-reimbursement term type contracts will be awarded for a base period of three years, with two one-year options for each contract. This is a recompetition of contracts with Univ. of Kansas, Univ. of North Carolina, Univ. of Arizona, and Univ. of Utah.

Inquiries: Carolyn Barker, Treatment Contracts Section, RCB, NCI, EPS Rm 603, 6120 Executive Blvd. MSC 7220, Bethesda, MD 20852-7220, tel: 301/496-8620, e-mail: barkerc@rcb.nci.nih.gov.

NCI Contract Awards

Title: Science Enrichment Program. Contractors: American Indian Science & Engineering Society, $145,869; Univ. of Kentucky Research Foundation, $148,965; Univ. of Southern California, $338,842; Univ. of Massachusetts, $535,900.